

Cast Versus Surgery for Displaced Intra-Articular Distal Radius Fractures in the Elderly a Randomized Clinical Noninferiority Trial (the DART Study)

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Background: Evidence supporting surgery in elderly patients with distal radius fractures is limited, but displaced fractures may benefit from surgery. This study aimed to determine whether casting is noninferior to surgery for patients aged 65 years or older with substantially displaced intra-articular (AO type C) distal radius fractures.

Methods: This multicenter randomized controlled noninferiority trial included 138 patients (mean age 76 years, SD 6.0) in 19 Dutch hospitals. 138 patients were randomized with a mean age of 76 years (SD 6.0). After 12 months, 126 patients (91%) completed the trial. All patients had a nonacceptable fracture position according to the guideline after reduction. Patients were randomized between casting and open reduction internal fixation (ORIF). The primary outcome was the Patient Rated Wrist Evaluation (PRWE) at the 1-year follow-up. Secondary outcomes included the Disability of the Arm, Shoulder, and Hand questionnaire; quality of life (measured by the EQ-5D-3L); range of motion; grip strength; and complications. Primary analyses were linear mixed models with an intention-to-treat approach.

Results: The mean PRWE score at 1-year follow-up for the casting group was 20.4 (95% CI, 15.3-25.6) and in the surgical group was 14.5 (95% CI, 9.9-19.0). The primary intention-to-treat crude analysis was inconclusive regarding noninferiority, with a between-group difference of 6.0 points (95% CI, -2.1 to 14.1) in favor of surgery. However, noninferiority was demonstrated after correction for baseline covariates and in both as-treated analyses. The surgical group had better grip strength but significantly more reoperations (i.e., hardware removal). Subgroup analysis showed greater benefits of surgery in physiologically younger patients, while more frail patients had no advantage.

Conclusions: The primary analysis did not demonstrate noninferiority of casting compared with surgery at 1-year follow-up in patients aged 65 years or older with substantially displaced intra-articular distal radius fractures. The benefit of surgery was consistent across multiple outcomes, most notably in the short term and for physiologically younger patients.

Level of Evidence: RCT. Level I evidence. See Instructions for Authors for a complete description of levels of evidence.

Introduction

Distal radius fractures account for approximately 18% of all fractures in the elderly¹. As the population ages, their incidence and associated healthcare burden are expected to rise². Since the introduction of locking plates, the incidence of surgery has markedly increased³⁻⁵. Locking plates enable ana-

tomical stabilization of osteoporotic bone through open reduction and internal fixation, allowing early mobilization.

Despite the increase in surgical interventions, their effectiveness has not been definitively proven in the elderly population⁶. In addition, surgery is considered more expensive and prone to complications⁷. The traditional alternative, closed

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reduction and casting, is considered safe and inexpensive, but may lead to malunion due to either imperfect reduction or redisplacement.

Over the past 10 years, several randomized controlled trials have been conducted on elderly patients with distal radius fractures. Most of these studies show that after 1 year, surgery does not yield clinically significantly better outcomes than casting⁸⁻¹⁴. This conclusion is also drawn by meta-analyses^{6,15-18}. However, some studies contradict this and report better outcomes with surgery, resulting in heterogeneity of study results¹⁹⁻²¹.

This trial addresses that uncertainty by focusing on elderly patients with substantially displaced intra-articular fractures, representing relatively severe cases. We hypothesized that casting is noninferior to surgery at 12 months.

Methods

Study Design

This is a noninferiority, multicenter randomized controlled trial, registered at ClinicalTrials.gov (NCT03009890), and conducted in accordance with the Consolidated Standards of Reporting Trials guidelines^{22,23}. Approval was obtained from the Medical Research Ethics Committees United (MEC-U: NL56858.100.16) and the institutional review boards of participating hospitals. The published protocol describes the design and methods in more detail²⁴. Protocol deviations are listed in the supplementary material.

Setting

This study was conducted in 19 hospitals in the Netherlands, including level 1 trauma centers and community hospitals. Data were collected at baseline and at 6 weeks and 3, 6, 9, and 12 months post-trauma. While the timing of recruitment and treatment could vary across individuals, all follow-up moments were determined relative to the date of injury.

Participants

Eligible patients were aged 65 years or older with an AO type C intra-articular distal radius fracture and a nonacceptable fracture position postreduction or after redisplacement within 3 weeks²⁵. According to the Dutch guideline, a nonacceptable position was defined as meeting at least 1 of the following criteria: $\leq 15^\circ$ radial inclination, ≤ 5 mm radial length from distal ulna (not the styloid) to radial styloid, $> 15^\circ$ dorsal tilt, $> 20^\circ$ volar tilt, or > 2 mm intra-articular gap/step-off. In this manuscript, we use the term substantially displaced fractures to emphasize that these cases exceeded these thresholds after initial management.

Randomization and Blinding

Patients were recruited within 3 weeks post-trauma by their treating physician or a research coordinator. After providing informed consent, they were randomized to surgery or casting²⁴. To ensure balanced age distribution, stratified randomization was used (65-74 and ≥ 75 years) with mixed block sizes (4, 6, 8). A web-based computerized randomization program was used to conceal treatment allocation. Blinding of patients

and physicians was not possible, but clinical measurements were conducted by research assistants who were not the patient's primary healthcare provider. The database was blinded for analysis.

Interventions and Crossover

All patients initially received closed reduction and a below-elbow forearm cast in the emergency department. In the casting group, this treatment was continued, with casts adjusted or exchanged after 1 week per local protocol. Duration was at the surgeon's discretion and not systematically recorded. Surgical patients underwent open reduction and internal fixation (ORIF) with a volar and/or dorsal plate, followed by optional casting for up to 2 weeks. Cross-over to surgery was allowed at the patient's or surgeon's discretion. Physical therapy was provided per local protocol, patient request, or physician recommendation²⁴.

Outcomes

The primary outcome measure was wrist function at 12 months, assessed using the Patient-Rated Wrist Evaluation (PRWE) score²⁶. This 15-item questionnaire assesses wrist pain and disability. Scores range from 0 (best) to 100 (worst)^{27,28}. A difference of 14 points was considered the minimal clinically important difference and used as the noninferiority margin²⁹.

Secondary outcomes included the Disabilities of the Arm, Shoulder, and Hand (DASH)³⁰; quality of life (EQ-5D-3L)^{31,32}; grip strength; radiographic outcomes; complications; and patient-reported satisfaction.

Baseline characteristics included demographics, comorbidities, dominant side, radiographic parameters, and frailty. Frailty was assessed using the validated Groningen Frailty Indicator (GFI)³³, which scores from 0 to 15; a score of ≥ 4 indicates frailty. It includes questions such as: 'Are you able to do the grocery shopping completely independently?' The complete GFI questionnaire is provided in the supplementary material.

ROM was measured with a goniometer and grip strength in kilograms using a hydraulic dynamometer. Values were expressed as percentages of the uninjured side.

Radiographic outcomes included radial inclination, length, angulation, and intra-articular step-off or gap, assessed at baseline and 3 months using standard posterior-anterior and lateral radiographs through PACS.

All adverse events within 1 year were documented, including complications related to implants or casting, nerve or tendon injury, CRPS, CTS, infection, reintervention, and death.

Sample Size

The sample size was based on a noninferiority design, a power of 90%, and a significance level (alpha) of 0.025. With a standard deviation of 23 and an MCID of 14 points for the PRWE score^{8,29}, a minimum of 57 patients per treatment group was needed. Further details are presented in the study protocol²⁴.

Statistical Analysis

Statistical analysis followed the predefined protocol²⁴. A linear mixed model with an intention-to-treat approach was used,

TABLE I Patient Characteristics.

	Casting Group		Surgical Group	
	N = 69	N	N = 69	N
Age, mean (SD)	75.7 (6.0)	69	75.6 (6.0)	69
Female, no. (%)	67 (97.1)	69	61 (88.4)	69
Dominant side injured, no. (%)	31 (48.4)	64	28 (44.4)	63
Diabetes mellitus, no. (%)	10 (16.1)	62	8 (12.7)	63
Corticosteroid use, no. (%)	4 (6.3)	63	3 (4.8)	63
Smoking, no. (%)	12 (19.0)	63	4 (6.5)	63
PRWE pretrauma, Mean (SD)	2.69 (7.9)	58	1.47 (6.1)	55
DASH pretrauma, mean (SD)	4.2 (7.6)	58	2.9 (6.2)	55
EQ-5D-3L pretrauma, mean (SD)	0.92 (0.11)	58	0.94 (0.09)	55
Frailty score ^a , mean (SD)	1.71 (1.60)	65	1.77 (1.96)	64
Frailty score ^a ≥ 4, no. (%)	8 (12.3)	65	11 (17.2)	64
Grip strength uninjured side ^b	38.5 (13.6)	66	44.8 (17.6)	64

DASH = disability of the arm shoulder and hand, EQ-5D-3L = EuroQol-5 dimension 3 level, and PRWE = patient rated wrist evaluation. ^aFrailty measured with the Groningen Frailty Index. ^bMeasured in kilograms.

with PRWE score as the dependent variable and treatment group, age, and baseline PRWE as fixed effects. Repeated measures were modeled with a random intercept. Group-by-time interaction assessed differences over time, and we also compared groups 'as treated'. Noninferiority was concluded if

the 97.5% confidence interval at 12 months excluded the 14-point margin. Sensitivity analyses adjusted for frailty³³, grip strength of the uninjured hand, and study center. Similar models were used for DASH and EQ-5D-3L. Categorical outcomes were tested with chi-square, continuous outcomes with t-tests. Subgroup analyses by chronological and physiological age were exploratory. Analyses were performed using SPSS v29 (IBM Corp, 2022).

Results

Participants

Between January 2017 and September 2021, 138 patients were enrolled and randomized to surgery (n = 69) or casting (n = 69). A patient flowchart is shown in Figure S1 (supplementary material). Owing to the involvement of 19 hospitals and limited study resources, it was not feasible to keep a screening log. Of the 19 participating hospitals, 6 included only patients aged 75 years or older due to perceived lack of equipoise. After 12 months, 126 patients (91%) completed follow-up. Baseline characteristics are presented in Table I.

Crossover occurred in 4 patients: 3 switched from casting to surgery within 6 weeks and 1 from surgery to casting immediately after randomization. As-treated analyses compared 67 casting and 71 surgery patients.

Primary Outcome

At the final follow-up, the mean PRWE score was 20.4 (95% CI 15.3-25.6) for casting and 14.5 (95% CI 9.9-19.0) for surgery. Fig. 1 shows the scores over time.

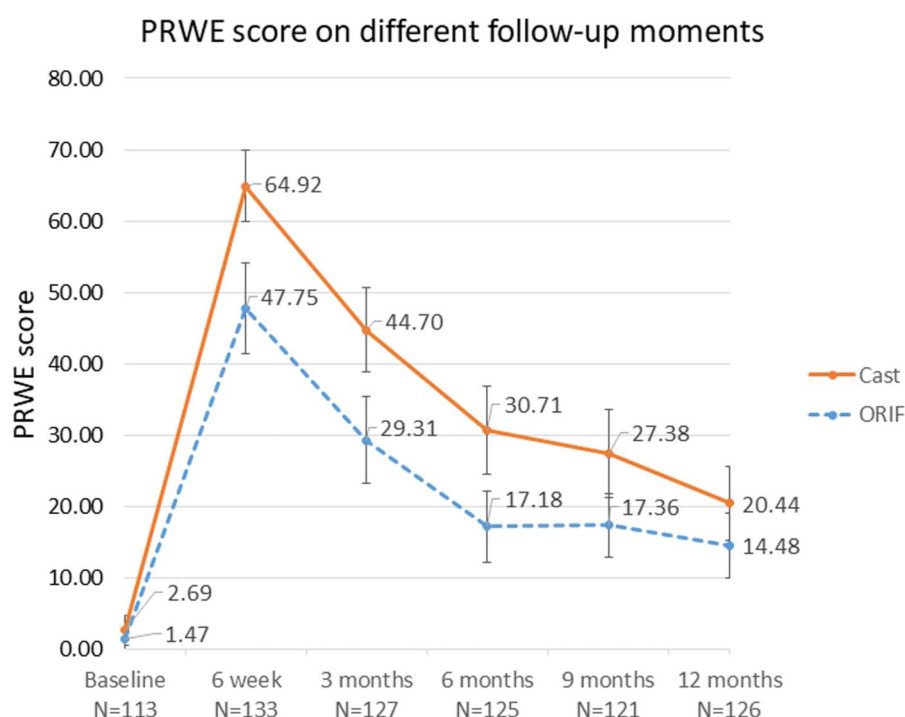


Fig. 1

PRWE scores are presented as means with 95% confidence intervals. PRWE = patient rated wrist evaluation.

TABLE II Mixed Model Analysis Group Differences Measured with the PRWE

Crude analysis*	N	Intention to treat analysis						As Treated Analysis					
		Between-Group Difference		Casting Group		Surgical Group		Between-Group Difference		Casting Group		Surgical Group	
		Estimate	95% CI	Mean	95% CI	Mean	95% CI	Estimate	95% CI	Mean	95% CI	Mean	95% CI
6 weeks	133	16.8	8.8 to 24.8	64.9	59.9 to 69.9	47.8	41.5 to 54.0	15.8	7.8 to 23.8	63.7	58.6 to 68.7	49.2	42.8 to 55.6
3 months	127	15.3	7.3 to 23.3	44.7	38.8 to 50.6	29.3	23.3 to 35.3	14.4	6.4 to 22.5	44.2	38.4 to 50.1	30.0	23.8 to 36.2
6 months	125	14.2	6.1 to 22.3	30.7	24.5 to 36.9	17.2	12.3 to 22.1	13.3	5.2 to 21.4	30.5	24.4 to 36.6	17.6	12.5 to 22.7
9 months	121	9.2	1.0 to 17.3	27.4	21.2 to 33.5	17.4	12.9 to 21.8	8.3	0.1 to 16.5	26.6	20.7 to 32.5	18.2	13.3 to 23.0
12 months	126	6.0	−2.1 to 14.1	20.4	15.3 to 25.6	14.5	9.9 to 19.0	5.1	−3.0 to 13.2	19.4	14.5 to 24.3	15.6	10.7 to 20.5
Sensitivity Analysis†	N	Estimate	95% CI					Estimate	95% CI				
6 Weeks	133	14.4	6.4 to 22.4					13.5	5.5 to 21.4				
3 Months	127	14.2	6.1 to 22.2					13.3	5.4 to 21.3				
6 Months	125	12.8	4.7 to 20.9					12.0	3.9 to 20.0				
9 Months	121	8.0	−0.2 to 16.2					7.2	−0.9 to 15.3				
12 Months	126	5.0	−3.1 to 13.1					4.1	−3.9 to 12.2				

PRWE = patient rated wrist evaluation. *The between-group difference at different time points corrected for age and baseline PRWE. †The between-group difference at different time points with additional adjustment for baseline frailty score and grip strength of the uninjured hand as fixed factors and center of inclusion as random intercept.

At 12 months, the primary intention-to-treat analysis showed a mean difference of 6.0 points (95% CI −2.1 to 14.1) favoring surgery (Table II). As the upper limit of the confidence interval slightly exceeded the 14-point noninferiority margin, the result was inconclusive²².

Fig. 2 shows a forest plot with results of the primary intention-to-treat analysis. Up to 6 months, the point estimate of the difference in favor of surgery exceeded the noninferiority threshold of 14 points. Up to 9 months after trauma the confidence interval of the difference between groups did not include zero, which indicates that a superiority analysis would have shown a statistically significant difference.

The intention-to-treat sensitivity analysis (adjusted for frailty score, grip strength, and center) showed a mean difference of 5.0 (95% CI, −3.1 to 13.1) in favor of the surgical group. This indicated noninferiority of casting compared with surgery. Both as-treated analyses also showed noninferiority of casting.

Secondary Outcomes

Table S1 (supplementary material) presents between-group differences for DASH, EQ-5D-3L, and VAS scores over time. Patient satisfaction was 86% for casting and 92% for surgery ($p = 0.24$). If injured again, 74% of casting patients and 87% of surgical patients would choose the same treatment ($p = 0.06$).

Complications

Table III presents all complications, which occurred in 9 patients (13%) with casting patients and 10 patients (15%) with surgery ($p = 0.81$). Hardware removal was significantly more common after surgery ($p < 0.012$).

Radiographic Results

Table S2 (supplementary material) presents radiographic characteristics before and after treatment. Post-treatment, all characteristics were better in the surgical group ($p < 0.05$).

Clinical Measurements

Figure S2 (supplementary material) shows grip strength and wrist range of motion. Grip strength was 4 times higher in the surgery group at 6 weeks, and twice as high at 3 months. At 12 months, ROM was similar, except for ulnar deviation, which remained better after surgery.

Subgroup Analyses

Figure S3 (supplementary material) shows mean PRWE scores over time by chronologic and physiologic age; Table S3 (supplementary material) presents subgroup results. At 12 months, the intention-to-treat analysis showed a between-group difference of 9.65 points on the PRWE (95% CI, −2.29 to 21.58) in patients aged 65 to 74 years and 3.78 (95% CI, −7.20 to 14.76) in those aged 75 years or older.

The median frailty score was 1, and frailty and age were weakly correlated ($R^2 = 0.06$). In patients with a frailty score ≥ 2 , the between-group PRWE difference at 12 months was −0.75. In physiologically young patient with a score of 0 to 1, the difference was 10.81 (95% CI, 0.73–20.88), which did not exceed the MCID.

Discussion

The formal result of this trial was inconclusive, so we cannot conclude that casting is noninferior to surgery 12 months after trauma for elderly with displaced intra-articular (AO type C)

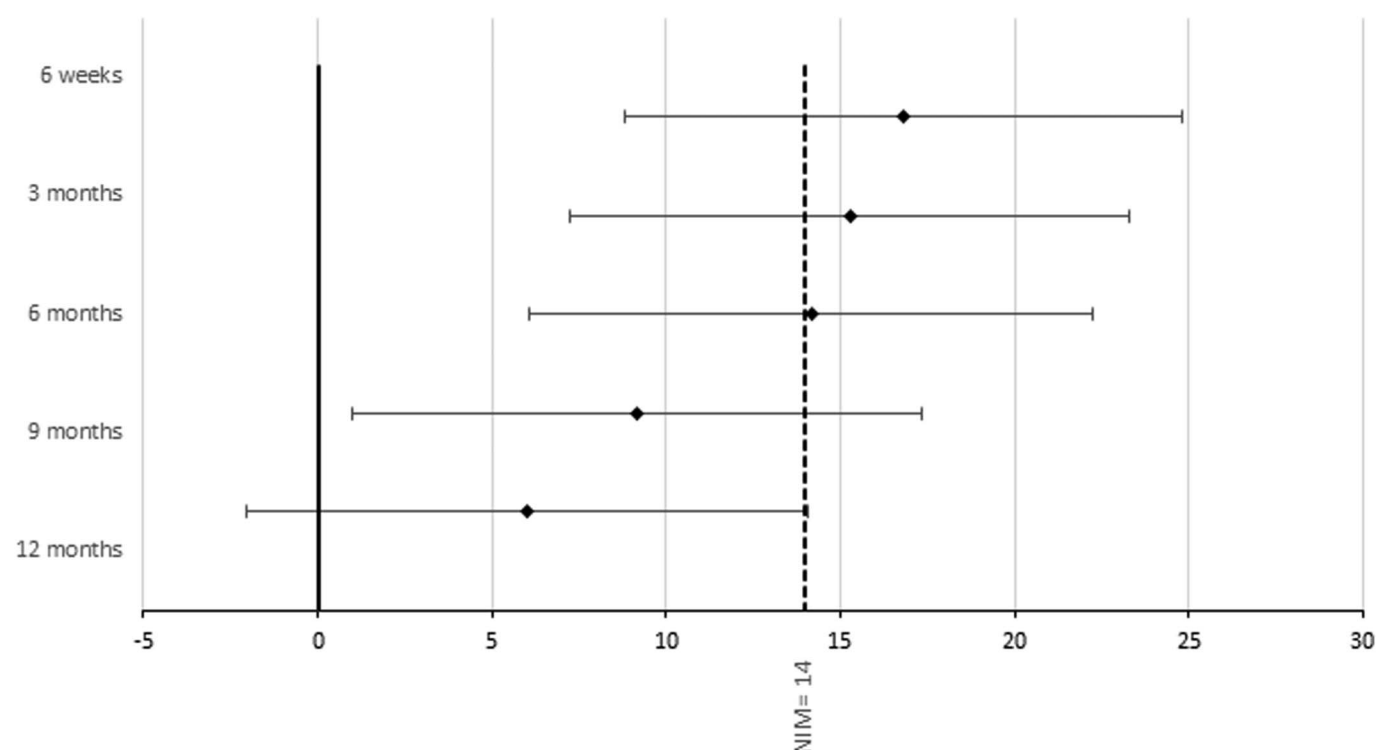


Fig. 2

A noninferiority plot showing the PRWE scores of the primary intention-to-treat crude mixed model analysis. The presented values indicate the between group differences of casting compared with the reference treatment which is surgery. The 95% confidence intervals around effect estimates are shown. Positive values indicate higher PRWE scores, corresponding with a worse outcome in the casting group. NIM = noninferiority margin, and PRWE = patient rated wrist evaluation.

distal radius fractures. As shown in the noninferiority plot (Fig. 2), the PRWE difference between groups exceeded the MCID up to 6 months post-trauma. A superiority analysis would show a statistically significant difference up to 9 months. Grip strength was also better in the surgical group for the first 6 months, supporting the early functional benefit of surgery. At the same time, it is important to note that the surgical group experienced a higher rate of additional surgery due to hardware removal.

Our study has several strengths. There were few cross-overs, and loss to follow-up was minimal. However, concerns exist regarding the generalizability of our findings. The DART study had a low inclusion rate. We observed that participating surgeons were hesitant to include patients outside their sense of equipoise, narrowing the study population beyond initial inclusion criteria. For instance, relatively young patients or those with more severe fractures were often treated surgically rather than randomized. While ethically commendable, this compromises external validity. However, even with the resulting study population, this study cannot conclude that casting is noninferior to surgery, which possibly further strengthens the case for surgical intervention.

Our inclusion criteria may reflect a more severely displaced subset than in many prior trials. For example, the studies by Martinez-Mendez, Mulders, and Selles included

patients with acceptable postreduction alignment^{19,34,35}. The trials by Lawson and Saving used fracture position before reduction as part of their inclusion but did not define specific radiographic criteria for postreduction alignment^{13,20}. The study by Hassellund most closely resembles ours in that it included fractures with poor alignment either after reduction or due to redisplacement¹⁰. Our focus on substantially displaced fractures after reduction complicated the inclusion phase but resulted in a population that was most likely to benefit from surgery.

Patients aged 65 years or older generally form a heterogeneous group. However, the study population had a median frailty of 1, which means it largely consisted of nonfrail patients. This may be due to our inclusion criteria (i.e., living independently) or due to a limited sensitivity of the Groningen Frailty score. Nevertheless, our subgroup analysis suggests that somewhat more frail patients do not seem to benefit from surgery, whereas more vital patients do benefit. This is in line with a retrospective study by Jayaram et al. that shows that active older adults who are surgically treated have more benefit³⁶.

Our study has a limited follow-up period of 12 months. Half of the patients underwent surgery which resulted in good fracture alignment in 72% of cases. The other half received casting for their substantially displaced fracture, resulting in

TABLE III Complications

	Casting Group (N = 69)	Surgical Group (N = 69)	p*
New onset palmar psoriasis, no. (%)	1 (1)	0 (0)	0.32*
Superficial radial nerve neuropathy, no. (%)	1 (1)	0 (0)	0.32
Exacerbation of CMC-1 osteoarthritis, no. (%)	2 (3)	0 (0)	0.15
Corrective osteotomy, no. (%)	1 (1)	0 (0)	0.32
CRPS, no. (%)	2 (3)	2 (3)	1
CTS, no. (%)	2 (3)	0 (0)	0.15
EPL rupture + surgical repair no. (%)	0 (0)	1 (1)	0.32
Median nerve lesion no. (%)	1 (0)†	0 (0)	0.32
Scheker prosthesis, no. (%)	1 (1)	0 (0)	0.32
Surgical PIN denervation, no. (%)	0 (0)	1 (1)	0.32
Prolonged hospitalization after surgery, no. (%)	0 (0)	1 (1)	0.32
Hardware removal, no. (%)	0 (0)	6 (9)	<0.012†
Surgical site infection, no. (%)	0 (0)	0 (0)	1
Death, no. (%)	0 (0)	0 (0)	1
Patients with any complications, No. (%)	9 (13.0)	10 (14.5)	0.81

CMC-1 = first carpometacarpal joint, CRPS = complex regional pain syndrome, CTS = carpal tunnel syndrome, EPL = extensor pollicis longus, and PIN = posterior interosseous nerve *Chi square. †Complication occurred after patient crossed over to surgical group. ‡Significant difference.

malunion. Long-term follow-up of these patients will demonstrate the consequences of these malunions such as potential osteoarthritis. Furthermore, distal radius fractures are highly heterogeneous. Predefined subgroup analyses are needed to identify patients and fractures types that benefit more from surgery. Since multiple randomized trials exist, an individual patient data meta-analysis will be a relevant next step. However, simple pooling of data may not do justice to subgroups of patients with more severe fractures or the physiologically younger patients. Our findings suggest that elderly patients with a distal radius fracture should not be treated as a homogeneous group, as factors such as fracture severity and physiological age may influence treatment outcomes.

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Appendix

eA Supplementary material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (<http://links.lww.com/JBJSOA/A889>). This content was not copyedited or verified by JBJS. ■

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